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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,737	03/04/2005	Enrico Cinti	37891	7870

116 7590 10/05/2005
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EXAMINER

YEBASSA, DESTA LETTA

ART UNIT PAPER NUMBER

1615

DATE MAILED: 10/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/526,737	Applicant(s) CINTI ET AL.	
	Examiner Desta L. Yebassa	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-38 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 26-38 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>03/04/05 and 05/23/05</u> | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Acknowledgment is made for the information disclosure statement (IDS) filed on 05/23/2005. Acknowledgment is also made for the foreign priority filed on 03/04/2005. Receipt is also acknowledged of the oath or declaration filed on 03/04/2005.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 26-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ashmead et al. (U.S. Patent No. 6,458,981) in view of Ciribolla (U.S. Patent No. (6,461,664) and Ashmead et al. (U.S. Patent No. 4,020,158).

Ashmead et al. teaches a composition and a method of preparing amino acid chelates that are essentially free of interfering ions. The compositions is prepared by

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reacting a calcium oxide or hydroxide, an amino acid, and a soluble metal sulfate salt in an aqueous environment at a ratio sufficient to allow substantially all of the ions present in solution to react forming a positively charged metal amino acid chelate having a hydroxide counter ion, a calcium sulfate salt, and optionally, water (abstract and column 5, lines 55-60), metal amino acid chelate or amino acid chelate shall include metal ions bonded to ligands forming heterocyclic rings that can be coordinate covalent, covalent, and or ionic at the carboxyl oxygen group (column 5, lines 20-25). Ashmead et al. also teaches the amino acid used are preferably one or more of the naturally occurring amino acid selected from the group consisting of methionine, alanine, arginine, asparagines, cysteine, glutamine, etc., and combinations thereof (column 6, lines 15-20). Furthermore, Ashmead et al. teaches preferred metals and soluble metal sulfate salts. Suitable metals include such as copper, zinc, iron, cobalt, magnesium manganese, chromium and combination thereof. Suitable preferred soluble metal sulfate salts selected from the group consisting of copper sulfate (CuSO_4), zinc sulfate (ZnSO_4), ferrous sulfate (FeSO_4), manganese sulfate (MnSO_4), cobalt sulfate (CoSO_4), magnesium sulfate (MgSO_4), ferric sulfate [$\text{Fe}_2 (\text{SO}_4)_3$], chromic sulfate [$\text{Cr}_2 (\text{SO}_4)_3$], and combination thereof (column 6, lines 25-30).

Ciribolla et al. teaches feed additive for agro-zootechnical use, in particular for alimentary use in the zootechnical sector, consisting of a chelate obtained by the reaction of methionine hydroxyl analogue with the carbonate of bivalent metal. The reaction is free from undesirable by-products, and the product is stable and effective in improving the main growth factors of the animals (abstract), the possible variants of a

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compound may be obtained by simply exchanging the bivalent metal (cuprous ion, zinc, manganous ion, cobalt, ferrous ion) chelated in each case with the organic molecule (column 4, lines 5-10).

Ashmead et al. teaches improvement of general health of animals by increasing the levels of metals in biological tissues through the administration of multiple metals in the form of metal proteinates (abstract), protein hydrolysates are prepared in either acidic or basic media, unhydrolyzed protein salts, in general, pass through the intestine largely intact with only small amounts being utilized, therefore the protein molecules are hydrolyzed to a polypeptide, peptide or amino acid stage prior to mixing with a metal salt to form a proteinate (chelate with a protein hydrolysate as the ligand (column 3, lines 40-50). Ashmead et al. also teaches the metal proteinates are vastly superior in being metabolically more assimilated in to the body compared to other chelates such as EDTA and chelates formed from other ligands such as ascorbic or citric acids (column 4, lines 30-40).

The primary reference, Ashmead et al., teaches a composition and a method of preparing amino acid chelates by reacting a calcium oxide or hydroxide, an amino acid, and a soluble metal sulfate salt in an aqueous environment to form a positively charged metal amino acid chelate having a hydroxide counter ion, a calcium sulfate salt, and optionally, water; preferably one or more of the naturally occurring amino acid selected from the group consisting of methionine, alanine, arginine, asparagines, cysteine, glutamine, etc., and combinations thereof; and preferred metals and soluble metal sulfate salts; metals such as copper, zinc, iron, cobalt, magnesium manganese,

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chromium and combination thereof; soluble metal sulfate salts such as copper sulfate (CuSO_4), zinc sulfate (ZnSO_4), ferrous sulfate (FeSO_4), manganese sulfate (MnSO_4), cobalt sulfate (CoSO_4), magnesium sulfate (MgSO_4), ferric sulfate [$\text{Fe}_2(\text{SO}_4)_3$], chromic sulfate [$\text{Cr}_2(\text{SO}_4)_3$], and combination thereof. The primary reference, does not teach feed additive for agro-zootechnical use, in particular for alimentary use in the zootechnical sector, consisting of a chelate obtained by the reaction of methionine hydroxyl analogue with the carbonate of bivalent metal; improvement of animal health by increasing the levels of metals in biological tissues through the administration of multiple metals in the form of metal proteinates which can be prepared in either acidic or basic media, vastly superior in being metabolically more assimilated in to the body compared to other chelates such as EDTA and chelates formed from other ligands such as ascorbic or citric acids. However, secondary references, teach feed additive for agro-zootechnical use, in particular for alimentary use in the zootechnical sector, consisting of a chelate obtained by the reaction of methionine hydroxyl analogue with the carbonate of bivalent metal; improvement of animal health of by increasing the levels of metals in biological tissues through the administration of multiple metals in the form of metal proteinates which can be prepared in either acidic or basic media, vastly superior in being metabolically more assimilated in to the body compared to other chelates such as EDTA and chelates formed from other ligands such as ascorbic or citric acids.

The prior arts recited as combined teach all the limitations of the instant claims. Therefore, It would have been deemed *prima Facie* obvious to one having ordinary skill in the art at the time of the invention to select any of the calcium oxide or hydroxide, an

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amino acid such as methionine, alanine, arginine, metals such as copper, zinc, iron, cobalt, magnesium manganese, chromium and combination thereof; and soluble metal sulfate salts such as copper sulfate (CuSO_4), zinc sulfate (ZnSO_4), ferrous sulfate (FeSO_4), manganese sulfate (MnSO_4), cobalt sulfate (CoSO_4), magnesium sulfate (MgSO_4), ferric sulfate [$\text{Fe}_2(\text{SO}_4)_3$], chromic sulfate [$\text{Cr}_2(\text{SO}_4)_3$], and combination thereof to form a metal amino acid chelate having a hydroxide counter ion, a metal sulfate salt, and optionally, water for use in human or animal feeding. Thus the invention as whole has been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Telephonic Inquiry

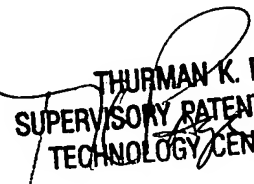
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Desta L. Yebassa whose telephone number is 571-272-8511. The examiner can normally be reached on Monday to Friday 8.00 am –6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Desta L. Yebassa, Ph.D.
Patent Examiner
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THURMAN K. PAGE
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